REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Claims 14-18 were pending in this application. Claim 18 was cancelled, claims 14-17 were amended and new claims 19-30 were added to further clarify the invention. Support for the amendment and new claims can be found in the application as originally filed. For instance, the original claims and the specification at page 1, line 13; page 5, lines 18-31; page 11, lines 16-24; and Example 3 (page 13) demonstrating the successful use of recombinant FlaA or P37 protein in an early Lyme disease diagnostic assay. Accordingly, no new matter has been introduced into the application as a result of the present amendment. Claims 14-17 and 19-30 are now pending in this application.

Turning to the Office action, claims 14-18 (now claims 14-17 and 19-30) were rejected under 35 U.S.C. section 102(a) as being anticipated by Ge et al. (*J. Bacteriology*, Jan. 1997, pp. 552-556)("Ge I") and Ge et al. (*Infection and Immunity*, July 1997, Vol. 65(7), pp.2992-2995) ("Ge II"). The Examiner contends that Ge discloses FlaA from *B. burgdorferi* and thus the presently claimed diagnostic reagent is anticipated. Applicants respectfully traverse this rejection.

As a threshold matter, a single source must contain all of the elements of the claim in order to anticipate a claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Missing elements may not be supplied by the skilled artisan or a disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Applicants respectfully submit that neither Ge I nor II can be said to anticipate the claimed invention.

Contrary to the Examiner's position, Ge states that "a putative flagellar outer sheath protein is not an immunodominant antigen associated with Lyme disease." See Ge II at page 2992, Abstract. Ge further states that FlaA (P37) "is ***not*** a good candidate for the serodiagnosis of Lyme disease." [Emphasis added]. See Ge II last paragraph and sentence on page 2994. Ge's conclusion was based on Western blot analyses of 19 human serum samples form Lyme disease

not occur as frequently as IgG antibodies of other specificities in late Lyme disease. See the specification at page 17, line 29 to page 18, line 5. Thus, Ge teaches away from the presently claimed diagnostic reagent for diagnosing Lyme disease and thus cannot be said to anticipate the claimed invention.

Ge merely states a problem in diagnosing early Lyme disease. He does not propose any solution involving the use of a diagnostic reagent comprised of FlaA or P37 protein. Indeed, Ge questions the significance of FlaA when he states that "[t]he precise function of *B. burgdorferi* FlaA is unclear." See Ge I at page 555, next to last paragraph. Contrary to Ge's teachings, the Applicants surprisingly discovered that FlaA is indeed a prominent antigen in the early humoral immune response to *B. Burgdorferi* infection and that it is surprisingly useful as a diagnostic reagent for the early detection of Lyme disease. See the specification at page 4, lines 5-12 and Example 3 on page 13. Withdrawal of the section 102(b) rejection of claims 14-18 (now claims 14-17 and 19-20) based on Ge I and II is in order and is respectfully requested.

Reconsideration of this application is respectfully requested and a favorable determination is earnestly solicited. The Examiner is invited to contact the undersigned representative if the Examiner believes this would be helpful in expediting prosecution of this application.

Respectfully submitted,

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APPENDIX A

14. A diagnostic reagent for early detection of Lyme disease comprising recombinant FlaA or P37 protein.

15. The diagnostic reagent of claim 14, said protein having the partial amino acid sequence as shown in SEQ ID NO.:2

16. The diagnostic reagent as in claim 15 wherein the recombinant FlaA or P37 protein is a fusion protein.

17. The diagnostic reagent as in claim 16 wherein the FlaA or P37 protein comprises a fusion partner that is approximately a 38 kDa T7 gene 10 product.

19. The diagnostic reagent of claim 14, said protein having the amino acid sequence of amino acids 1-319 of SEQ ID NO.:2.

20. A diagnostic reagent for early detection of Lyme disease produced using a method for producing recombinant FlaA or P37 protein comprising: providing freshly transformed host cells; constructing a DNA expression vector containing an expressible FlaA encoding DNA sequence; transforming a suitable host cell with said expression vector; plating out transformed host cells; preparing large scale primary cell cultures from transformed host cells taken from a fresh transformant colony; and inducing FlaA or P37 protein expression from said host cells in culture to obtain a recombinant FlaA or P37 protein.

21. A diagnostic reagent as in claim 20 comprising the entire amino acid sequence encoded by the nucleic acid sequence as shown in SEQ ID NO: 1.

22. A diagnostic reagent as in claim 20 comprising the partial amino acid sequence as shown in SEQ ID NO: 2.

23. A diagnostic reagent as in claim 20 comprising the partial amino acid sequence encoded by the nucleic acid sequence as shown in SEQ ID NO: 3.

24. A diagnostic reagent as in claim 20 wherein the recombinant FlaA or P37 protein is a fusion protein.

25. A diagnostic reagent as in claim 20 wherein the recombinant FlaA or P37 protein comprises a fusion partner that is approximately a 38 kDa T7 gene 10 product.

an E. Coli cell.

27. A diagnostic reagent as in claim 14 comprising an amino acid sequence or fragment thereof selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 3.

28. A host cell containing the nucleic acid sequence of claim 15 or a complement thereof.

29. An expression vector comprising the nucleic acid sequence of claim 15 or a complement thereof.

30. A diagnostic reagent for detection of Lyme disease comprising an amino acid sequence as in claim 15 which is substantially antigenic to B. burgdorferi antibodies.